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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/619,047	07/18/00	LENG J	CHEM1110

EXAMINER	
PAK,Y	
ART UNIT	PAPER NUMBER
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DATE MAILED: 06/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application No.	Applicant(s)	
	09/619,047	LENG, JAY	
	Examiner	Art Unit	
	Yong Pak	1652	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *May 3, 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Claims 1-65 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to luciferase, classified in class 435, subclass 189.

II. Claims 9-20 and 48, drawn to DNA encoding luciferase and a method of producing luciferase, classified in class 435, subclass 189.

III. Claim 21-33, drawn to a method of identifying a protease activity modulator, classified in class 435, subclass 8.

IV. Claims 34-42, drawn to a method of identifying an inhibitor of apoptosis, classified in class 435, subclass 8.

V. Claims 43-45, drawn to antibody against luciferase, classified in class 530, subclass 387.9.

VI. Claims 46-47 and 65, drawn to a kit for detecting caspase activity and a method for detecting caspase activity, classified in class 435, subclass 6.

VII. Claims 49-54, drawn to a fusion protein, classified in class 435, subclass 189.

VIII. Claims 55-60, drawn to DNA encoding a fusion protein, vector containing said DNA, host cell containing thereof and a method of producing fusion protein, classified in class 435, subclass 189.

IX. Claims 61-64, drawn to a polypeptide comprising a localization sequence, a protease cleavable recognition sequence and a luciferase polypeptide sequence, classified in class 435, subclass 189.

The inventions are distinct, each from the other because of the following reasons:

The protein of Inventions I, VII and IX are patentably distinct as having different structures, functions, substrate specificities, and utilities. DNA of Inventions II and VIII are patentably distinct as encoding enzymes with different structures, functions, substrate specificities, and utilities.

Inventions I-II, V and VII-IX are patentably distinct because a protein, a DNA and an antibody are different compounds, each with its own chemical structure and function, and they have different utilities. DNA molecule of inventions II and VIII are not limited in use to the production of polypeptide of invention I and VII and can be used as a hybridization probe, and protein of invention I and VII can be obtained by a materially different method such as by biochemical purification. The structure of an antibody of Invention V is not predictable from the structure of the protein of invention I and an antibody can cross-react with various proteins.

Inventions I and III - IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the enzyme of

Invention I can be used for the production of the antibodies of Invention V and in the methods of Invention III-IV.

The methods of III-IV and VI are patentably distinct as having different effects and utilities. The methods of Inventions III-IV and VI are also patentably distinct as directed to materially different methods employing different products. Invention III-IV uses enzyme and Invention VI uses DNA.

This application contains claims directed to the following patentably distinct species of the claimed invention: a polypeptide having luciferase activity and comprising different protease recognition sequence, SEQ ID NO:2 and SEQ ID NO:4 have different structures and utilities.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 3, 7, 11, 13, 23, 25, 28, 34, 36, 39, 51 and 63-64 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Ms. Haile on May 14, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

May 16, 2001

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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